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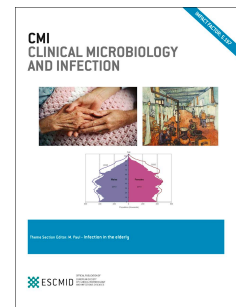
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# Accepted Manuscript

Developing core elements and checklist items for global hospital antimicrobial stewardship programmes: a consensus approach

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## 1 CONSENSUS PAPER

### 2 Developing core elements and checklist items for global hospital antimicrobial 3 stewardship programmes: a consensus approach

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**ABSTRACT**

**Objectives.** With increasing interest in hospital antimicrobial stewardship (AMS) programmes globally, there is a strong demand for core elements of AMS to be clearly defined based on principles of effectiveness and affordability. To date, efforts to identify such core elements have been limited to Europe, Australia, and North America. The aim of this study was to develop a set of core elements and their related checklist items for AMS programmes that should be present in all hospitals, regardless of resource availability, worldwide.

**Methods.** A literature review was performed by searching Medline and relevant websites to retrieve a list of core elements and items that could be relevant globally. These core elements and items were evaluated by an international group of AMS experts using a structured modified Delphi consensus procedure, using two-phased online in-depth questionnaires.

**Results.** The literature review identified 7 core elements and their related 29 checklist items from 48 references. Fifteen experts from 12 countries in 6 continents participated in the consensus procedure. Ultimately, all 7 core elements were retained, as well as 28 of the initial checklist items plus 1 that was newly suggested, all with  $\geq 80\%$  agreement; 20 elements and items were rephrased.

**Conclusions.** This consensus on core elements for hospital AMS programmes is relevant to both high and low-to-middle income countries and could facilitate the development of national AMS stewardship guidelines and adoption by healthcare settings worldwide.

## INTRODUCTION

Antimicrobial resistance, particularly antibiotic resistance in bacteria, is a global threat, making antimicrobial stewardship (AMS) programmes necessary in all hospitals worldwide [1–3]. A recent review conducted by ESGAP (ESCMID Study Group for Antimicrobial stewardship) authors found that many definitions exist for the abbreviation AMS [2]. The authors suggested that it is best to view the collective daily actions within AMS as a strategy, and they proposed the following definition: “Antimicrobial stewardship is a coherent set of actions which promote using antimicrobials in ways that ensure sustainable access to effective therapy for all who need them” [2]. The absence of a universal definition for AMS combined with a lack of international guidance and standards are among the many barriers to the implementation of these programmes globally, especially in low and middle-income countries (LMICs) [2,4]. In North America, Europe, and Australia, collaborative groups have identified, through a consensual approach, core elements considered essential for successful AMS programmes [5–9]. These core elements, often bundled into checklists, offer healthcare providers a pragmatic and measurable means of developing, implementing, and measuring the impact of hospital AMS programmes. Their applicability, contextual relevance, and value in other geographies, cultures, and resource settings, particularly LMICs, have not been previously explored.

Our objective was to identify existing core elements for hospital AMS programmes and assess their broader global relevance. This was done by undertaking a literature review followed by a structured consensus procedure involving experts.

## METHODS

Our objective was to identify a set of core elements and their related checklist items [10], describing the essential and minimum standards for AMS programmes in hospitals worldwide.

### *Group of experts*

The steering committee (CP, FB, ASL, AT, SG, RL) invited 15 experts (all other coauthors) to participate in this study. Experts from different backgrounds (infectious diseases specialists, clinical microbiologists and clinical pharmacists) were selected based on their recognized expertise in AMS across various geographic settings in six continents (North America = 2, South America = 2, Europe = 5, Africa = 2, Asia = 3, Australia = 1), all having extensive hands-on experience with AMS in LMICs and most of them serving as experts for health authorities and policy-makers on the AMS topic.

### *Literature review and website search*

In August–September 2017, the steering committee (six researchers) performed a narrative literature review of PubMed with the following key words: (antibiotic or antimicrobial) and stewardship and (review or guidelines or standard or core or checklist), in addition to a website search (relevant agencies and organizations, such as World Health Organization (WHO) or European Centre for Disease Prevention and Control (ECDC), to search for existing core elements for hospital AMS programmes. Only reviews, guidance/guidelines and consensus documents were included. Additional references were identified by the 15 experts, with no language restriction (all authors assisted with translation when required). Data was extracted by two junior researchers and double checked by two senior researchers. Based on the final list of references [3–50], the steering committee

compiled summary tables (listing all core elements and checklist items found, with their corresponding references), which were made available to the experts. CP and SG developed an initial set of core elements and their related checklist items, to be assessed by the experts, based on the summary tables, selecting the elements and items they thought might be relevant worldwide. A core element was defined as a broad category of actions/a strategy within an AMS programme (e.g. Education), whereas checklist items described specific actions/interventions within a specific core element. Several checklist items were then listed under each core element.

#### *Consensus procedure*

The list of core elements and checklist items based on the literature review and the website search (as well as the detailed summary tables) was presented to the group of 15 experts for a modified Delphi consensus procedure [51], consisting of two surveys (first and second rounds). Invitation to participate in the survey was sent by email. A teleconference was organised early November by the steering committee, to explain the objectives and methods to all experts, and reply to their questions.

For the first round (November 2017), the list of core elements and checklist items were converted into an internet-based questionnaire using SurveyMonkey (Palo Alto, California, USA). Respondents were asked to select all core elements and checklist items they felt were essential worldwide and should be part of AMS programmes in all hospitals and in all countries, using a “yes/no” option; a “comments” box was provided for each element/item, including suggestions for rephrasing. Elements and items were (1) selected if agreement was  $\geq 80\%$  (i.e., 12 experts or more); (2) held for reassessment during the second round if agreement was between 70% and 79% (11 experts); (3) rejected if agreement was  $< 70\%$  (fewer than 11 experts). Experts were also asked to suggest new elements and items for



further assessment, in addition to rephrasing. Newly suggested elements and items were considered for inclusion in the second round if at least three experts made the same suggestion.

During the second round (December 2017), all previously accepted, newly added, and rephrased elements and items were presented in a second internet-based questionnaire, which was sent to all experts who had participated in the first round. Experts were asked to rate the newly suggested items and the items held for reassessment, as well as to choose the best phrasing when appropriate (the selected phrasing was the one with >50% agreement). A “comments” box for open-ended feedback was available for all elements and items.

## RESULTS

### *Literature review and website search*

We identified 48 relevant references (written in Chinese, English, French or Spanish) [3–50] and came up with an initial set of 7 core elements and 29 checklist items.

### *Consensus procedure*

All 15 experts participated in the two rounds of the survey. During the first round, all 7 core elements were selected, as well as 27 out of the 29 checklist items, while 1 item was held for reassessment, 1 was rejected, and 2 additional items were newly suggested by 3 experts. Rephrasing was suggested for 27 elements/items, and comments were added for 14 of them. During the second round, 2 out of 3 items were selected, and the final phrasing was decided upon (newly suggested phrasing was chosen in 20 out of 27 cases). The procedure is summarised in Figure 1, with the final set of 7 core elements and 29 checklist items presented in Boxes 1 to 7 (Appendix S1 presents the full details of the procedure). The core elements were as follows: senior hospital management leadership towards AMS (Box 1, 3 checklist items), accountability & responsibilities (Box 2, 7 items), available expertise on infection management (Box 3, 2 items), education & practical training (Box 4, 2 items), other actions aiming at responsible antimicrobial use (Box 5, 8 items), monitoring & surveillance (Box 6, 4 items), and reporting & feedback (Box 7, 3 items).

## DISCUSSION

Based on a pragmatic literature review and a structured consensus procedure, we developed minimum core elements and checklist items that could be relevant to hospital AMS programmes worldwide. Even though most of these checklist items may not currently exist in most hospitals in low-income countries, we included all of them on the list because our main objective was to identify universally relevant, essential elements and items based on the best available evidence. These 7 core elements and their related 29 checklist items could be adapted and adopted locally depending on factors such as clinical setting and resource availability. They provide a baseline of key elements required to start hospital AMS programmes, and could be further modified and used for accreditation/certification, benchmarking, or scrutiny/performance purposes [52,53]. We were purposely as generic as possible in the phrasing of elements and items so that countries could adapt them to their own situations, for example regarding the composition of AMS teams.

When comparing our 7 core elements and 29 checklist items with the list developed by the Centers for Disease Control and Prevention (CDC) in the United States, we found that both lists of core elements are very similar in content, even though the phrasing is different [6]. The CDC also validated 7 core elements: leadership commitment, accountability, drug expertise, action, tracking, reporting, and education [6]. The CDC developed a shorter list of 22 related checklist items [6], 12 of them being quite close to the checklist items we selected. Our list of 29 checklist items is, however, both more comprehensive and more generic, reflecting our objective of being relevant to any hospital worldwide.

Implementing AMS programmes in hospitals is one aspect of the comprehensive One Health strategy needed to tackle antimicrobial resistance [1]. The importance of having such programmes in the community or primary care setting, that are aligned with hospital programmes, cannot be underestimated [53]. Implementing a hospital AMS programme is

also not possible without a strong commitment from policymakers, senior leadership, and national initiatives to guarantee access to good-quality, equitably priced essential antimicrobials [54]. In addition, education for the public and health professionals is a necessary prerequisite to initiating strong and lasting AMS programmes.

Our work has several limitations. We did not conduct a systematic literature review but are confident we have not missed significant references, as we have included recent systematic reviews on the topic, and additional references were identified by a large panel of AMS experts, with no language restriction [3]. The number of experts involved in the consensus procedure was relatively small, even though the number was close to previously published consensus procedures [5,55]. Like all consensus procedures, ours was biased by the opinions of the experts, who all primarily had the perspective of the steward. Experts who serve in administrative roles in healthcare and thus represent more of the perspective of a hospital might have had different answers.

In conclusion, we propose here an evaluation framework for hospital AMS programmes that could be relevant across both resource-rich and resource-limited contexts. Evaluating its value and then its feasibility and measurability in a range of geographic and resource settings, with a broader stakeholder group should be the next step.

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**TRANSPARENCY DECLARATIONS**

There is no conflict of interest to declare for any of the authors.

EC is affiliated with the National Institute for Health Research Health Protection Research Unit (NIHR HPRU) in Healthcare Associated Infections and Antimicrobial Resistance at Imperial College London in partnership with Public Health England (PHE). The views expressed are those of the author and not necessarily those of the NHS, the NIHR, the Department of Health or Public Health England.

The opinions expressed in this article are those of the authors and do not necessarily reflect the views of the Centers for Disease Control and Prevention.

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**Box 1. Core element 1: Senior hospital management leadership towards antimicrobial stewardship**

Accompanying comment: *This section relates to governance of the programme by hospital executives, and specifies how senior hospital management supports the antimicrobial stewardship programme.*

Checklist item 1.1:

**Has your hospital management formally identified antimicrobial stewardship as a priority objective for the institution and included it in its key performance indicators?**

Checklist item 1.2:

**Is there dedicated, sustainable and sufficient budgeted financial support for antimicrobial stewardship activities (e.g., support for salary, training, or IT (information technology) support)?**

Checklist item 1.3:

**Does your hospital follow any (national or international) staffing standards for antimicrobial stewardship activities (e.g. number of full-time equivalent (FTE) per 100 beds for the different members of the antimicrobial stewardship team)?**

Accompanying comment: *These staffing standards should ideally be set at national level.[56]*

409 **Box 2. Core element 2: Accountability & responsibilities**

<p>Checklist item 2.1:</p> <p><b>Does your hospital have a formal/written antimicrobial stewardship programme/strategy accountable for ensuring appropriate antimicrobial use?</b></p> <p>Accompanying comment: <i>This should be based on existing national/international guidelines and/or an existing national strategy.</i></p>
<p>Checklist item 2.2:</p> <p><b>Does your hospital have a formal organizational multidisciplinary structure responsible for antimicrobial stewardship (e.g., a committee focused on appropriate antimicrobial use, pharmacy committee, patient safety committee or other relevant structure)?</b></p> <p>Accompanying comment: <i>This antimicrobial stewardship committee can be either stand-alone or embedded into another committee structure (e.g. pharmacy committee, patient safety committee or other relevant structure). In all cases, this antimicrobial stewardship committee is explicitly in charge of setting and coordinating the antimicrobial stewardship programme/strategy in its mandate/terms of reference.</i></p>
<p>Checklist item 2.3:</p> <p><b>Is there a healthcare professional identified as a leader for antimicrobial stewardship activities at your hospital and responsible for implementing the programme?</b></p>
<p>Checklist item 2.4:</p> <p><b>Is there a document clearly defining roles, procedures of collaboration and responsibilities of the antimicrobial stewardship team members?</b></p> <p>Accompanying comment: <i>We refer here to the core operational team of healthcare professionals (led by the clinical leader) who will implement the antimicrobial stewardship strategy 'daily on the ground'. This is different from the antimicrobial stewardship committee, which is a larger formal organizational structure that includes antimicrobial stewardship team members and other relevant professionals and administrators. In resource-limited settings or small hospitals, although desirable, it is sometimes difficult to have an antimicrobial stewardship team; in that case, the antimicrobial stewardship clinical leader will implement the antimicrobial stewardship programme. The composition of the (usually multidisciplinary) antimicrobial stewardship team is flexible and should be based on existing international recommendations and adapted to the local context.</i></p>
<p>Checklist item 2.5:</p> <p><b>Are clinicians, other than those part of the antimicrobial stewardship team (e.g. from the ICU, Internal Medicine and Surgery) involved in the antimicrobial stewardship committee?</b></p>
<p>Checklist item 2.6:</p> <p><b>Does the antimicrobial stewardship committee produce regularly [indicate minimum time] a dedicated report which includes e.g. antimicrobial use data and/or prescription improvement initiatives, with time-committed short term and long term measurable goals/targets for optimising antimicrobial use?</b></p>
<p>Checklist item 2.7:</p> <p><b>Is there a document clearly defining the procedures of collaboration of the antimicrobial stewardship team/committee with the infection prevention and control team/committee?</b></p>

**Box 3. Core element 3: Available expertise on infection management**

Checklist item 3.1:

**Do you have access to laboratory/imaging services and to timely results to be able to support the diagnosis of the most common infections at your hospital?**

Accompanying comment: *A separate checklist on laboratory capacity and presence of quality assurance should be developed at national/international level. [49,57] These services can be onsite or not.*

Checklist item 3.2:

**In your hospital are there, or do you have access to, trained and experienced healthcare professionals (medical doctor, pharmacist, nurse ...) in infection management (diagnosis, prevention and treatment) & stewardship willing to constitute an antimicrobial stewardship team?**



413 **Box 4. Core element 4: Education & practical training**

Checklist item 4.1:

**Does your hospital offer a range of educational resources to support staff training on how to optimise antimicrobial prescribing?**

Accompanying **comment:** *These resources can be developed locally or not, and can use multiple formats.*

Checklist item 4.2:

**Do the antimicrobial stewardship team members receive regular training in antimicrobial prescribing and stewardship?**

Accompanying comment: *This training is usually not offered at the hospital level, but likely to be at a regional, national or international level. The hospital should however ensure that members of the antimicrobial stewardship team are adequately trained, according to local/regional/national requirements.*

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**Box 5. Core element 5: Other actions aiming at responsible antimicrobial use**

Checklist item 5.1:

**Is a multidisciplinary antimicrobial stewardship team available at your hospital (e.g., greater than one trained staff member supporting clinical decisions to ensure appropriate antimicrobial use)?**

Checklist item 5.2:

**Does your hospital support the antimicrobial stewardship activities/strategy with adequate information technology services?**

Accompanying comment: *The level of requirement needs to be defined at local/regional/national level. This could include, for example, measurement of antimicrobial use.*

Checklist item 5.3:

**Does your hospital have an antimicrobial formulary (i.e. a list of antimicrobials that have been approved for use in a hospital, specifying whether the drugs are unrestricted, restricted [approval of an antimicrobial stewardship team member is required] or permitted for specific conditions)?**

Accompanying comment: *This might be based on national recommendations, or the WHO Essential Medicines List.*

Checklist item 5.4:

**Does your hospital have available and up-to-date recommendations for infection management (diagnosis, prevention and treatment), based on international/national evidence-based guidelines and local susceptibility (when possible), to assist with antimicrobial selection (indication, agent, dose, route, duration) for common clinical conditions?**

Checklist item 5.5:

**Does your hospital have a written policy that requires prescribers to document an antimicrobial plan (includes indication, name, dosage, duration, route and interval of administration) in the medical record or during order entry for all antimicrobial prescriptions?**

Checklist item 5.6:

**Does the antimicrobial stewardship team review/audit courses of therapy for specified antimicrobial agents or clinical conditions at your hospital?**

Checklist item 5.7:

**Is advice from antimicrobial stewardship team members easily available to prescribers?**

Checklist item 5.8:

**Are there regular infection and antimicrobial prescribing focused ward rounds in specific departments in your hospital?**

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417 **Box 6. Core element 6: Monitoring & surveillance (on a continuous basis)**

Checklist item 6.1:

**Does your hospital monitor the quality of antimicrobial use at the unit and/or hospital wide level?**

Accompanying comment: *This can be done for example by undertaking point prevalence surveys or audits, assessing appropriateness of infection management and antimicrobial prescription (e.g. indication, choice and duration of antibiotic therapy in pneumonia or surgical prophylaxis according to policy/guidance).*

Checklist item 6.2:

**Does your stewardship programme monitor compliance with one or more of the specific interventions put in place by the stewardship team (e.g. indication captured in the medical record for all antimicrobial prescriptions)?**

Checklist item 6.3:

**Does your hospital monitor antibiotic susceptibility rates for a range of key bacteria?**

Checklist item 6.4:

**Does your hospital monitor the quantity of antimicrobials prescribed/dispensed/purchased at the unit and/or hospital wide level?**

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419 **Box 7. Core element 7: Reporting & feedback (on a continuous basis)**

Accompanying comment: *All these reports should also be shared with the hospital management leadership.*

Checklist item 7.1:

**Does your stewardship programme share hospital-specific reports on the quantity of antimicrobials prescribed/dispensed/purchased with prescribers?**

Checklist item 7.2:

**Does your stewardship programme share facility-specific reports on antibiotic susceptibility rates with prescribers?**

Checklist item 7.3:

**Are results of audits/reviews of the quality/appropriateness of antimicrobial use communicated directly with prescribers?**

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421 **Figure 1. The Delphi consensus procedure: Flow chart**

